

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and  
RONALD LEWIS

*Plaintiffs,*

v.

ALEX AZAR II, in his official capacity as the  
Secretary of the Department of Health and  
Human Services.

*Defendant.*

Case No. 2:20-cv-00738-CMR

**PLAINTIFFS' OPPOSITION TO MOTION TO DISMISS**

Plaintiffs Lynn Oxenberg and Ronald Lewis have both, tragically, been diagnosed with brain cancer (GBM) and have been treating it using tumor treatment field therapy (TTFT) coverage of which they sought from Medicare. With the help of TTFT, a diagnosis of GBM is not a death sentence. Nevertheless, the Secretary seeks to sentence Plaintiffs to terminal litigation by forcing them to repeatedly litigate whether TTFT is medically reasonable and necessary and a Medicare covered treatment for them.

Having won multiple times in decisions that the Secretary did not appeal, inexplicably, other ALJs, considering the same treatment for the same patients, decided that TTFT was not medically reasonable and necessary and a Medicare covered benefit for Plaintiffs. Unless reversed by this Court, the ALJ decisions denying Plaintiffs their substantive statutory right to payment will be binding on Plaintiffs<sup>1</sup> and will also result in the loss of Plaintiffs' right to a payment "Mulligan"

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<sup>1</sup> See 42 C.F.R. § 405.1048(a) ("The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties[.]").

under other portions of the statute.

Now that Plaintiffs have brought suit to redress these harms, the Secretary contends that Plaintiffs cannot complain that their rights are being violated.

That would be a neat trick were it true.

Of course, the Secretary's position is without merit.

## **I. INTRODUCTION**

A brief explanation of the situation facing Plaintiffs may assist the Court in appreciating the circumstances faced by them.

Having been diagnosed with a GBM, Plaintiffs are being treated using a TTFT device manufactured by Novocure, Inc. marketed under the brand name "Optune." While the Optune device does not kill the cancer, it helps prevent their spread by interfering with the growth of the cancer cells. Thus, in order to work, Plaintiffs will need to use the Optune device for the remainder of their (hopefully extended) life.

The Optune device is rented on a monthly basis at a cost of more than \$10,000 per month.<sup>2</sup> Relying on assumed Medicare payment, to date, Novocure has provided the treatment to Plaintiffs while their claims have proceeded through the system for eventual payment. Other than the cases at issue, each of Plaintiffs' claims has eventually been paid.

However, in the present case, at least one ALJ denied Plaintiffs' claims for coverage and simultaneously held that Novocure would receive no payment for the treatment provided to

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<sup>2</sup> The Optune device is tuned to interfere with the particular cancer the patient is suffering from and the arrays that deliver the electrical field are mapped on the patients skull to direct treatment to the location of the cancer. Over time, this mapping may need to be updated and the Optune system itself has consumable components (e.g., arrays for use with the device, gels for increasing transduction through the skin). Further, the Optune device also collects data on the treatments provided and this data is then transmitted to the patient's doctors and various reports generated to assist in the treatment protocol.

Plaintiffs. Accordingly, if Novocure does not want to risk providing treatment for free to Plaintiffs (to whom they owe no duty), then Novocure has two options - both of which make Plaintiffs personally liable for the cost. First, Novocure can refuse to provide Plaintiffs treatment unless they pay \$10,000/month out-of-pocket. Second, Novocure can refuse to provide Plaintiffs treatment unless they sign an agreement saying that, if Medicare does not pay, Plaintiffs will pay (*i.e.*, an Advanced Beneficiary Notice (ABN)).

The Secretary contends that Plaintiffs are not harmed until sometime after they are put to the choice of foregoing treatment (and thereby hastening their own death) or encumbering whatever assets they may have and hope to leave their family.<sup>3</sup> It is precisely to avoid that choice and to vindicate their rights under the statute that Plaintiffs bring this suit.

Further, the Secretary seeks to have his cake and eat it too. First, the Secretary denies Plaintiffs their substantive statutory right to payment and orders somebody with no duty to Plaintiffs to provide treatment for free. As a result of this decision, Plaintiffs also lose their right to a payment “Mulligan” under the statute. Second, the Secretary contends that Plaintiffs cannot complain about the loss of their rights.

## II. DISCUSSION

Plaintiffs have standing because they have been denied their substantive statutory right to Medicare benefits, and that, in and of itself, results in injury. The assertion that someone else should pay for their treatment has no bearing on the denial of their substantive statutory right and standing to bring this case.<sup>4</sup>

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<sup>3</sup> The Court can well imagine that many people might forego treatment and a hastened death rather than render themselves and their families penniless.

<sup>4</sup> Similarly, in other contexts, the fact that a plaintiff may receive offsetting funds from a source different than the tortfeasor does not defeat standing under the collateral source rule.

Further, pursuant to 42 U.S.C. § 1395pp, Medicare beneficiaries are entitled to a “Mulligan” on payment. That is, Medicare will pay a rejected claim as long as the beneficiary neither knew nor had reason to know that the claim would not be paid. However, this is a one-time proposition and once a beneficiary is put on notice that a claim may not be paid, they lose their right to payment under § 1395pp. In this case, Plaintiffs have also suffered injury because, if the denial is not reversed, Plaintiffs will lose their “Mulligan” under 42 U.S.C. § 1395pp. Plaintiffs’ loss of their “Mulligan” constitutes either a present harm or substantial risk of a future harm. Regardless of how considered, Plaintiffs have standing.

**A. Plaintiffs Have Standing Based on Denial of Their Substantive Statutory Right**

As described by the Supreme Court in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), a plaintiff must satisfy three requirements to meet Article III’s requirements for standing. First, a plaintiff must have suffered an injury in fact, *i.e.*, an invasion of a legally protected interest, which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of. Third, it must be likely that the injury will be redressed by a favorable decision. *Id.* at 560.

Congress may create a statutory right or entitlement, the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially-cognizable injury in the absence of the statute. *See Warth v. Seldin*, 422 U.S. 490, 514 (1975). That is, with respect to certain statutes, the alleged violation of a substantive, statutorily-created right is, alone, a sufficient injury in fact to give rise to Article III standing. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n. 3 (1973) (“Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute.”); E. Chemerinsky, *FEDERAL JURISDICTION* (7<sup>th</sup> ed. 2016) § 2.3.2 at 73 (“Violations of rights created by statute are also

sufficient for standing purposes.”). Thus, in these circumstances, economic injury is not the touchstone of standing. Rather, it is the denial of a substantive statutory right.<sup>5</sup>

Medicare benefits are an entitlement created by Congress, the denial of which confers standing. *See* 42 U.S.C. § 405(g) (“Any individual ... may obtain a review of such decision”); 42 U.S.C. § 1395ff(a)(1)(A) (“whether an individual is entitled to benefits”); 42 U.S.C. § 1395k(a)(1) (“entitlement to have payment made to him or on his behalf”) / (a)(2) (“entitlement to have payment made on his behalf”); *Heckler v. Ringer*, 466 U.S. 602, 620 (1984) (“the Medicare Act provides both the substance and the standing for [the plaintiff’s] claim”). Importantly, the rights created by the statute are personal to the beneficiaries and not independent rights of providers or anyone else.

Thus, because Plaintiffs have been denied their Congressionally created entitlement to Medicare coverage, they have suffered an injury, and that injury can be redressed by a decision ordering coverage.

Claims that Plaintiffs lack economic injury are merely an effort to contradict the Supreme Court’s decisions in *Warth* and *Linda S.* It is well settled that a “concrete injury” may, or may not, be an “economic injury.” *See, e.g.*, 33 Wright, Koch, and Murphy, FEDERAL PRACTICE & PROCEDURE § 8335 (Supp. 2018) (“It is also clear that harms need not be economic in nature to be concrete enough for standing[.]”). Multiple courts have rejected the notion that economic injury is a requirement for standing, including in Medicare claim denial cases. *See, e.g.*, *Anderson v. Sebelius*, 2010 WL 4273238 at \*3 (D. Vt. Oct. 25, 2010) (although administrative law judge waived plaintiff’s financial liability for services delivered, plaintiff still had standing); *Longobardi*

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<sup>5</sup> With regard to the amount of injury required to establish standing, an “identifiable trifle” is enough. *U.S. v. Students Challenging regulatory Agency Procedures*, 412 U.S. 669, 689 n. 14 (1973) (“an identifiable trifle is enough for standing to fight out a question of principle”).

*v. Bowen*, 1988 WL 235576 at \*2 (D. Conn. Oct. 25, 1988) (plaintiff had standing even though Medicaid paid claims denied by Medicare); *Martinez v. Bowen*, 655 F.Supp. 95, 99 (D. New Mexico 1986) (same); *Ross v. Bank of America, N.A. (USA)*, 524 F.3d 217, 222 (7<sup>th</sup> Cir. 2008) (“Moreover, the fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing.”).

For example, *Ryan v. Burwell*, 2015 WL 4545806 at \*5-7 (D. Vt. July 27, 2015), involved circumstances virtually identical to the present case. There, the plaintiffs sought home health care benefits. Though they had been previously granted those benefits multiple times by ALJs, they subsequently received a denial from an ALJ and that denial was upheld by the Council. Importantly, though their claims were denied by Medicare, those same claims were subsequently covered by Medicare and the plaintiffs suffered no financial liability.

Just as in this case, the Secretary moved to dismiss on standing grounds alleging that the beneficiaries suffered no injury. In a thorough decision, the court rejected the Secretary’s argument noting that the denial resulted in a loss of the statutory right to payment and also would result in a loss of the right to payment under the Medicare “Mulligan” statute. *Id.* at \*7 (referring to 42 U.S.C. § 1395pp). Thus, the court held that the beneficiaries had standing.

The Secretary relies on the Supreme Court’s decision in *Spokeo, Inc. v. Robins*, 136 S.Ct 1540 (2016) as somehow overruling all prior decisions on standing. That is simply not the case. As detailed in *Spokeo*, the mere violation of a “procedural right” *may*, or may not, be sufficient to confer standing. *Id.* at 1549. That said, there is a difference between a “procedural right” and a “substantive right.” As cogently explained by one court:

A “procedural right” is defined as “a right that derives from legal or administrative procedure; a right that helps in the protection or enforcement of a substantive right.” In contrast, a “substantive right” is “a right that can be protected or enforced by law; a right of substance rather than form.”

*See Bock v. Pressler & Pressler, LLP*, 254 F.Supp.3d 724, 732 (D. N.J. 2017) (internal citations and quotations omitted). Here, as set forth in the Complaint, Plaintiffs allege a violation of their substantive right to payment of their Medicare claims by the Secretary. That the Secretary asserts that someone other than Medicare should bear the expense of the claims does not change the violation of Plaintiffs substantive right to Medicare payment by the Secretary. Thus, again, Plaintiffs have standing.

*Thole v. U.S. Bank N.A.*, 140 S.Ct. 1615 (2020) is also relied on by the Secretary and is equally inapposite. At issue in *Thole* was a defined benefit pension plan. While the plaintiffs contended that the plan was mismanaged, regardless, the plaintiffs would have received the same benefits due under the plan. As emphasized by the Supreme Court:

If Thole and Smith were to *lose* the lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny less. If Thole and Smith were to *win* the lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny more.

*Id.* at 1619 (emphasis in original). Accordingly, no order from the Court would change the plaintiff's position, the plaintiffs lacked injury and, therefore, standing. By contrast, in the present case, Plaintiffs have been denied their substantive statutory right to Medicare payment for their treatments and, therefore, have suffered an injury. Again, Plaintiffs' right is to Medicare payment for their treatments, not to the treatments themselves. If the Court rules in Plaintiffs' favor as to the underlying issue of coverage/collateral estoppel, they will receive their substantive statutory right to payment by Medicare. By contrast, if Plaintiffs' claim is denied, they will not receive their payment for their treatments by Medicare. *Thole* does not support the Secretary's argument.

**B. Plaintiffs Additionally Have Standing Based on Loss of Substantive Statutory Right**

If the decision denying coverage is not reversed in the case, then Plaintiffs will suffer the present loss of their right to recovery under Medicare's "Mulligan" provisions. Considered

alternatively, Plaintiffs will suffer a substantial risk of economic injury. Under either approach, Plaintiffs have standing to bring their claims.

### **1. Plaintiffs Present Loss of Right**

Beyond the denial of their substantive statutory rights, it is incorrect to say that Plaintiffs will suffer no injury if the claim denial is not reversed. As the *Ryan* and *Anderson* courts recognized, a decision denying coverage that stands has significant effects on financial liability for subsequent claims for coverage. Pursuant to 42 U.S.C. § 1395pp(a):

Conditions prerequisite to payment for items and services notwithstanding determination of disallowance: Where—

- (1) a determination is made that, by reason of section 1395y(a)(1) or (9) of the title or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of the subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u(b)(3)(B)(ii) of the title, and
- (2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by the subchapter, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of the subchapter), as though section 1395y(a)(1) and section 1395y(a)(9) of the title did not apply and as though the coverage denial described in subsection (g) had not occurred. *In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of the section), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services.*

(emphasis added). These provisions constitute a kind of “Mulligan.” That is, under the statute, even if a claim is properly rejected, the Secretary will still pay the claim if the beneficiary neither



knew nor should have known that the claim would be rejected. However, this is a one-time “Mulligan” and the statute provides that “thereafter” the beneficiary will be charged with such knowledge and no longer qualify under the provision. *See also* 42 C.F.R. § 411.404(b).

Thus, the present harm to Plaintiffs is being charged under the statute with knowledge of the denied claim, resulting in loss of their right to payment under the statute. That this is a present harm is demonstrated by the fact that, unless reversed now, Plaintiffs would have no ability to challenge the denial of coverage in this case when their right to receive payment on subsequent claims is adjudicated. Thus, for example, if a subsequent claim by Plaintiffs is denied, the denial of coverage in this case, may leave them personally liable under 42 U.S.C. § 1395pp in that later case. Were that to happen, they would have no ability in the subsequent suit to challenge the decision in this case which laid the foundation for that denial. *See, e.g., Jayne v. Herman*, 706 F.3d 994, 1000 (9<sup>th</sup> Cir. 2013) (“To the extent that the plan pre-determines the future, it represents a concrete injury that plaintiffs must, at some point, have standing to challenge. That point is now, or it is never.”) (internal citations and quotations omitted). This is a present harm which confers standing.

## **2. Plaintiffs Have Standing Because They Face Financial Liability**

While the loss of Plaintiffs’ statutory right, standing alone, constitutes a present harm, even were the Court to find that injury does not exist until Plaintiffs are deemed personally, financially liable, then they also have standing. As described by the Supreme Court, for standing purposes, a future injury “may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur.” *Department of Commerce v. New York*, 139 S.Ct. 2551, 2565 (2019) (citing *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). *See also Spokeo*, 136 S.Ct. at 1549 (“risk of real harm”). With regard to “substantial risk”, as noted by the Seventh Circuit:

[S]tanding in the Article III sense does not require a certainty or even a very high probability that the plaintiff is complaining about a real injury, suffered or threatened. A suit to redress an injury to the plaintiff is a “case” or “controversy” within the meaning that the courts have imprinted on these words of Article III of the Constitution as long as there is some nonnegligible, nontheoretical, probability of harm that the plaintiff’s suit if successful would redress. As we have noted repeatedly, the fact that a loss or other harm on which a suit is based is probabilistic rather than certain does not defeat standing.

*Mainstreet Organization of Realtors v. Calumet City, Ill.*, 505 F.3d 742, 744 (7<sup>th</sup> Cir. 2007).

In this case, as in *Ryan*, Plaintiffs suffer from a chronic/incurable condition and will need tumor treatment field therapy (TTFT) treatment for the remainder of their lives. That Plaintiffs will have claims beyond those at issue in the case is, therefore, certain and not speculative.

Because of the loss of Plaintiffs’ right to recovery under 42 U.S.C. § 1395pp, if this case is not reversed, Plaintiffs suffer the risk of being held personally, financially liable for their treatments at any time. That is a substantial risk of harm sufficient for standing purposes and, again, Plaintiffs have standing. The harm is much more than a “trifle” and plainly confers standing. *See SCRAP*, 412 U.S. at 689 n. 14 (“an identifiable trifle is enough”).

In other briefing, the Secretary has cited *Clapper v. Amnesty Int’l, USA*, 568 U.S. 398 (2013), for the proposition that “allegations of possible future injury are not sufficient.” The Secretary’s effort to rely on *Clapper*’s test for standing under the “certainly impending/imminent” prong is misplaced because the Supreme Court has long recognized that standing may also be based on a “substantial risk that harm will occur.” Indeed, post-*Clapper*, the Supreme Court affirmed the long-standing rule. *See Dept. of Commerce*, 139 S.Ct. at 2565.

To give but one example of the application of the principle, in *Dimarzo v. Cahill*, 575 F.2d 15 (1<sup>st</sup> Cir. 1978), prisoners sued a county jail alleging unconstitutional conditions. In particular, the prisoners alleged that the jail (built in 1814 with an addition in 1884) was a fire trap that put them at risk of injury or death. The Commissioner of Corrections moved to dismiss, alleging that

there was no standing because the prisoners could not show that they would “inevitably suffer physical injury or death from fire.” *Id.* at 18. In rejecting the claim and finding standing, the First Circuit held: “One need not wait for the conflagration before concluding that a real and present threat exists.” *Id.* See also 13A Wright, Miller, & Cooper, FEDERAL PRACTICE AND PROCEDURE § 3531.4 (Supp. 2018) (collecting cases).

Likewise, Plaintiffs need not wait until they are put to the choice of financial ruin or a hastened death before they have standing.

### **C. Further Response to The Secretary’s Arguments**

Before turning to the Secretary’s substantive claims, Plaintiffs address the Secretary’s contention that Medicare benefits are not an entitlement and that the denial of Medicare benefits is a mere “procedural” violation. Mot. at 8. That contention is simply unsupportable. First, the Medicare statute itself describes the benefit as an “entitlement to have payment made to him or on his behalf.” See, e.g., 42 U.S.C. § 1395k(a)(1). See also *Taransky v. Sec. of U.S. Dept. Health and Human Services*, 760 F.3d 307, 310 (3<sup>rd</sup> Cir. 2014) (“Medicare is a federal entitlement program that provides health insurance benefits to qualified elderly and disabled individuals.”). Thus, rather than the Secretary having “discretion to approve or reject claims” (Mot. at 8), the Secretary *must* provide benefits pursuant to the statute (and subject to any regulations issued in accordance with the statute). Pursuant to 42 U.S.C. § 405(g), a denial of benefits is subject to judicial review under the “substantial evidence” standard (for fact conclusions) and otherwise any standard applicable under the Administrative Procedure Act (e.g., arbitrary and capricious) rather than a mere abuse of discretion standard. Accordingly, entitlement to Medicare benefits is a substantive right rather than a mere procedural right.

In sum, Congress has created a substantive statutory right to Medicare benefits and

provided for judicial review if those benefits are denied in a manner not in accordance with the statute. In the present case, Plaintiffs allege that their right to benefits has been denied in violation of the Medicare Act and seek judicial review of the same. Thus, Plaintiffs have standing.

Along these same lines, the Secretary alleges that Plaintiffs' injury is not "concrete." Mot. at 8. As noted in *Spokeo*, a "concrete" injury must be "*de facto*", that is, it must actually exist and be real and not "abstract." *Spokeo*, 136 S.Ct. at 1548. Here, there is nothing "abstract" or speculative about Plaintiffs' injury – they have been denied payments they are entitled to under the statute.

Moreover, the Secretary's overall effort to rely on *Spokeo* as somehow reworking traditional standing analysis is misplaced. As the Third Circuit recognized in *In re: Horizon Healthcare Services, Inc. Data Breach Litigation*, 846 F.3d 625 (3<sup>rd</sup> Cir. 2017), *Spokeo* did no such thing and affirmed traditional notions of standing. *Id.* at 638 ("In the absence of any indication to the contrary, we understand that the *Spokeo* Court meant to reiterate traditional notions of standing."). Instead, *Spokeo* was largely concerned with the distinction between "procedural rights" and "substantive rights" and held that even the violation of mere "procedural rights" may be sufficient for standing. Traditional standing analysis applies.

The Secretary's effort to rely on *Wheeler v. Travelers Ins. Co.*, 22 F.3d 534 (3<sup>rd</sup> Cir. 1994) is misplaced and readily distinguishable. Mot. at 8-9. *Wheeler* concerned a private party seeking to litigate whether under Pennsylvania's "no fault" insurance program, Medicare was a "primary" or "secondary" payer of medical benefits and whether Medicare should receive recoupment for benefits paid but for which the private insurer might be liable. Importantly, in *Wheeler*, the plaintiff's claims were paid by Medicare and the plaintiff sought to force the private insurer to pay them as well (though any such payment would have to be transferred to Medicare).

On appeal, the Third Circuit held that the plaintiff lacked both Constitutional and prudential standing. *Id.* at 528-39. Constitutionally, the Circuit Court held that: “Wheeler never has had anything to gain from this lawsuit.” Prudentially, the Circuit Court held that Wheeler was not “best suited” to assert claims between the insurers and Medicare. Thus, the case was dismissed for lack of standing.

The distinctions between *Wheeler* and the present case are readily apparent. First, given that the claims were actually paid by Medicare, there was no allegation of a denial of a substantive statutory right. Second, in light of the payment by Medicare and the apparent one-time nature of the event, there was no loss of the right to a “Mulligan” under the statute. Both of those are present in this case. As indicated, under the statute, the right to payment by Medicare is a right of the beneficiary’s and not a right of the suppliers/providers. Thus, the Plaintiffs in this case are seeking to vindicate their own rights, rather than a right of some other party as was the case in *Wheeler*. Overall, if Plaintiffs are successful, they will have preserved their right to a Medicare “Mulligan” and also received their right under the statute for Medicare payment of their claims (rather than relying on a third party that owes them no duty to provide treatment).<sup>6</sup>

Similarly misplaced is the Secretary’s effort to rely on *California Clinical Lab Assn’n v. Sec. of HHS*, 104 F.Supp.3d 66 (D.D.C. 2015). There, a laboratory sought to rely on a beneficiary to utilize the expedited process of challenging an LCD in district court alleging that the entire LCD process was unconstitutional. *See* 42 U.S.C. § 1395ff(f)(2). The district court dismissed the claim because the beneficiary was not, in fact, denied her right to bring suit under § 1395ff(f)(2). With

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<sup>6</sup> Likewise, the Secretary’s effort to rely on *Koons v. XL Ins. America, Inc.*, 620 Fed.Appx. 110 (3<sup>rd</sup> Cir. 2015) is equally misplaced. Mot. at 9. *Koons* is not even a Medicare case and was dismissed because the plaintiff was both fully indemnified and had assigned his right to recovery to a third party (Erie) after the suit was filed. Thus, *Koons* had nothing to gain from the suit. By contrast, as indicated above, Plaintiffs in this case do have something to gain.

regard to the beneficiary's claim to standing because the denial of her pharmacogenomic claim conferred standing, the district court denied that as well. While the district court did not do an analysis of the plaintiff's personal right to Medicare payment and how that related to standing, the court did engage in a discussion about future claims and noted that there was no contention that future claims on the same basis had or would be ordered and on that basis, *inter alia*, found future harm hypothetical/speculative. *Id.* at 79-80.

Again, that decision is readily distinguished from the present case. First, given the ongoing need for TTFT coverage, that there will be claims going forward is not speculative or hypothetical. Indeed, given the lack of an indication of future claims, the *California Clinical* court did not address the loss of right to a Medicare "Mulligan." By contrast, in the present case, Plaintiffs will have ongoing claims and, unless the decision in this case is reversed, will have lost their right to a "Mulligan" under the statute. Second, in the present case, Plaintiffs are not standing as proxy seeking to challenge an LCD or the LCD issuance process. Instead, Plaintiffs seek to vindicate their own rights under the statute.

The Secretary cites to three TTFT cases where similar issues were the subject of motion practice. Mot. at 1, *e.g.* (citing *Pehoviack v. Azar*, 2020 WL 5814116 (C.D. Cal. July 22, 2020), *Komatsu v. Azar*, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020), and *Prosser v. Azar*, 2020 WL 6266040 E.D. Wisc. Oct. 21, 2020)). While citing these cases, the Secretary did not disclose that neither the *Pehoviack* nor the *Prosser* cases are final. Indeed, both *Pehoviack* and *Prosser* are the subject of appellate practice. Importantly (and in a demonstration of the urgency of these cases), both Mrs. Komatsu and Mrs. Pehoviack passed away before appeals in their cases could be completed. Indeed, in light of Mrs. Pehoviack's passing, a motion to dismiss the appeal and vacate the judgment below is pending at the Ninth Circuit. With regard to the *Prosser* case, oral argument

(on an expedited bases) at the Seventh Circuit is scheduled for January 13, 2020. In Plaintiffs' view, the Secretary should reveal that decisions are non-final before it asks a court to rely on them.

Substantively, the *Komatsu* court largely adopted the reasoning of *Pehoviack* issued by a different judge in the same district. Further, the *Prosser* court explicitly adopted the same reasoning as *Pehoviack* in a two-page decision issued promptly in order to ensure appellate review. In any event, none of those courts had the benefit of the extensive briefing now being provided.

### III. CONCLUSION

As detailed above, Plaintiffs have standing because they have been denied their substantive statutory right to payment of their claims by Medicare. In addition/the alternative, Plaintiffs have standing because, unless reversed, Plaintiffs will lose their right to a payment "Mulligan" under the statute (either considered as a present harm or as a "substantial risk" of subsequent harm). The Secretary's motion to dismiss should be denied.

Dated: November 30, 2020

Respectfully submitted,

/s/ Nicholas R. Rodriguez

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**CERTIFICATE OF SERVICE**

I hereby certify that on this date, a true and correct copy of the foregoing Plaintiffs' Opposition to Motion to Dismiss was filed and served upon all counsel of record through the Court's CM/ECF.

Dated: November 30, 2020

/s/ Nicholas R. Rodriguez